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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/631,470	04/12/1996	STALEY BROD	D5716CIP2	5157

27851 7590 02/02/2004

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EXAMINER	
SAYALA, CHHAYA D	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

CAE

Office Action Summary	Application No.	Applicant(s)	
	08/631,470	BROD, STALEY	
	Examiner	Art Unit	
	C. SAYALA	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10,12-15 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-10, 12-15 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-3, 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Sobel (US Patent 5780021, which is an equivalent of WO 94/02154).

Sobel teaches the oral administration (col. 13, line 10+) of a Type I interferon for auto-immune diseases, including diabetes, listed at col 1 and col. 2, lines 5-30 in the same doses claimed herein, at col. 4, lines 10-25. The species to be treated are listed at col. 4 and col. Col. 11, lines 35+. Note that at col. 10, the patentee notes that the treatment reduces inflammatory response, which would in turn reduce the levels of inflammatory cytokines, and at col. 11, line 20, that it inhibits recurrent diabetes.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 5-10, 12-15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sobel and Cummins, Jr.

Sobel teaches all of the limitations of the claims listed and discussed in paragraph 2 above. The patentee does not teach alternate day dosing and does not teach MS in particular, although he does teach the therapy for auto-immune diseases and it is well known that MS is an auto-immune disease. See references listed in PTO-form 892, which shows state of the art and what is well known. Cummins also teaches all of the limitations of the claims, including using alpha interferon for MS, except the amount claimed and alternate day dosing. However, he does show that a daily dosage is possible, as a single dosage or as divided, and administered in a multiple daily dose regimen. The reference also teaches a staggered regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc.,

it would have been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS. It is worthwhile to note that even though Sobel teaches the same amounts as claimed, patentee states that the precise amount will depend on the judgement of the attending physician based on considerations of age, weight and condition of the patient.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Response to Amendment

Applicant's arguments filed 11/03/03 have been fully considered but they are not persuasive.

Although applicant admits in his response at page 16, that Sobel teaches administering an effective amount of Type I interferon to a mammal to prevent or treat autoimmune disorders, he also argues that patentee's statements are not adequately enabled and that patentee's statements are "generalized". He states that Sobel only teaches that the incidence of diabetes is reduced and the onset of diabetes is delayed. In fact, the claims are to "treating" diabetes, in Sobel. Discussions of enablement in an issued patent and discussions pertaining to "ingestion upon oral administration" have been adequately discussed in the decision of the Board of Patent Appeals and Interferences and applicant is respectfully referred to those parts of that decision which refer to and address such arguments by applicant. The references teach administering the same compound to treat the same condition, "auto-immune diseases", in the same

way, "oral administration". To distinguish the instant claims from prior art for patentability, based on the limitation "such that the type one interferon is ingested upon oral administration", is unconvincing and unpersuasive, particularly when the BPA&I decision establishes that no special meaning for the word "ingest" has been attributed by the specification. As for Sobel not teaching multiple sclerosis, the rejection is under 35 USC 103 and it is noted that it is well known that the terms "auto-immune" disease include multiple sclerosis, as discussed in Cummins, Jr., and applied in paragraph 4, above. Cummins teaches administering, orally, the same interferon for MS. It would be reasonable to expect the person of ordinary skill in the art to follow the guidelines of Sobel for dosing.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. SAYALA at Group 1761, telephone number (703) 308-3035.

The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-0661.

C. SAYALA
Primary Examiner
Group 1700.